IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8887**

Bartle, J. June 6, 2012

William L. Neilson ("Mr. Neilson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Frances M. Rizzo, Mr. Neilson's fiancée, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In May, 2004, claimant submitted a completed Green Form to the Trust signed by his attesting physician, John P. Orchard, M.D., F.A.C.C. Dr. Orchard is no stranger to this litigation. According to the Trust, he has attested to at least 550 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated September 17, 2002, Dr. Orchard attested

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3. (...continued)
(Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

in Part II of Mr. Neilson's Green Form that he suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $578,687.[4]

In the report of claimant's echocardiogram, Dr. Orchard stated that claimant had "[m]oderate [mitral regurgitation]." Dr. Orchard, however, did not specify a percentage as to the level of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In November, 2005, the Trust forwarded the claim for review by Rohit J. Parmar, M.D., F.A.C.C. one of its auditing cardiologists. In audit, Dr. Parmar concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because his

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

echocardiogram demonstrated only mild mitral regurgitation. Dr. Parmar explained that:

> Mild mitral regurgitation is noted by Singh Criteria. The [echocardiogram] technician has erroneously included low velocity flow in the [mitral regurgitant area] tracing. This has given an exaggerated [mitral regurgitant area]/LAA ratio. By my calculation the [mitral regurgitant area]/LAA ratio is 11%, consistent with mild [mitral regurgitation].

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Mr. Neilson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[5] In contest, claimant argued that there was a reasonable medical basis for Dr. Orchard's representation of moderate mitral regurgitation and that there were no errors made by the echocardiogram technician. In support, Mr. Neilson submitted two additional Green Form Part II's, one completed by Nadeeem V. Ahmad, M.D. and the other completed by Richard A. Goldstein, M.D. Both Dr. Ahmad and Dr. Goldstein attested that Mr. Neilson suffered from moderate mitral regurgitation.

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Neilson's claim.

The Trust then issued a final post-audit determination, again denying Mr. Neilson's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Mr. Neilson's claim should be paid. On November 20, 2006, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 17, 2007, and claimant submitted a surreply on June 9, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor,

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attending physician's finding that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson explained:

> In reviewing the echocardiogram from 9/17/02, my visual estimate is that there is normal left ventricular size with preserved systolic function, and mild mitral

> regurgitation. The parasternal views are of good quality, and reveal only mild mitral regurgitation. The quality of the apical views is mildly suboptimal. I measured the mitral regurgitant jet and the left atrial area in four representative cardiac cycles. I was not able to measure the RJA/LAA in the same frame because the mitral regurgitation was only visible in early systole (an indication that is only mild), whereas the standard time to measure the left atrial size is at end systole when it is the largest. My measurements for mitral RJA/LAA are 2.6 $cm^2$/17.2 $cm^2$, 2.6 $cm^2$/22.5 $cm^2$, 3.1 $cm^2$/ 24.3 $cm^2$, and 2.8 $cm^2$/24.6 $cm^2$. These RJA/LAA ratios are 15%, 12%, 13%, and 11%, all of which are less than 20%, and are consistent with mild mitral regurgitation.
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> The three RJA measurements on the tape are erroneously traced and all include low velocity flow, which is incorrect when tracing the jet of mitral regurgitation. Only high velocity mosaic jets should be included in the tracing of mitral regurgitation. All of the jets occur only in early systole, which is also consistent with mild mitral regurgitation.
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> ....
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> In summary, a reasonable echocardiographer would interpret the severity of this mitral regurgitation as mild.... However, there is no reasonable medical basis for the Attesting Physician's claim that William Neilson has moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant makes a number of challenges to the methodology used by Dr. Abramson.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not

adequately refute the findings of the auditing cardiologist or the Technical Advisor. Specifically, neither Mr. Neilson nor his physicians directly confront the auditing cardiologist's determination that he suffered from mild mitral regurgitation with an RJA/LAA ratio of 11% and that low velocity flow was improperly included by the echocardiogram technician when tracing the RJA. Similarly, claimant does not challenge Dr. Abramson's conclusion that the RJA measurements on the echocardiogram tape included low velocity flow and that all of the jets occurred early during systole consistent with mild mitral regurgitation. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that the inclusion of low velocity flow relates only to the cardiologist's "impression" of the echocardiogram. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;

(7) failing to take a claimant's medical history; and

(8) overtracing the amount of claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Parmar and Dr. Abramson concluded that claimant's echocardiogram improperly included low velocity flow in the tracing of claimant's mitral regurgitation. And, as noted, Dr. Abramson found that "[a]ll of the jets occur only in early systole, which is also consistent with mild mitral regurgitation." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnoses and Green Form answers.[7]

In addition, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that he had moderate mitral regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's finding of moderate mitral regurgitation cannot be medically reasonable where the auditing cardiologist concluded that claimant's echocardiogram demonstrated an RJA/LAA ratio of 11% and the

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7. For this reason as well, we reject claimant's argument that the Green Forms completed by Dr. Ahmad and Dr. Goldstein provide "additional proof" that Mr. Neilson had moderate mitral regurgitation.

Technical Advisor concluded that claimant's echocardiogram demonstrated RJA/LAA ratios of 15%, 12%, 13%, and 11%. Adopting claimant's argument would expand the range for moderate mitral regurgitation and would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, we reject claimant's characterization of the reasonable medical basis standard, as set forth in his response to the Trust's statement of the case, that the "Attesting Physician's diagnosis must be accepted unless it is so slanted or of such an obvious misleading nature it could not be accepted by a reasonable cardiologist with Level II training." We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. As discussed above, Dr. Parmar and Dr. Abramson both determined, and Mr. Neilson does not adequately dispute, that Dr. Orchard's finding of moderate mitral regurgitation was unreasonable. Contrary to claimant's argument, Dr. Parmar and Dr. Abramson properly applied the reasonable

medical basis standard established under the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Neilson's claim for Matrix Benefits and the related derivative claim submitted by his fiancée.